UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,034	10/02/2003	Jeffrey C. Rapp	AVI-034CIP	1081

26739 7590 07/01/2008
AVIGENICS, INC.
111 RIVERBEND ROAD
ATHENS, GA 30605

EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
07/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/679,034	**Applicant(s)** RAPP ET AL.
	Examiner Michael C. Wilson	**Art Unit** 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2008*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-29,31 and 53-68* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-15, 17-29, 31 53-68* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 16, 30, 32-52 have been canceled. Claims 53-68 have been added. Claims 1-15, 17-29, 31 and 53-68 are pending and under consideration.

When pointing to support for amendments, please provide the page and line number - pointing only a paragraph number in a 110 page specification impedes examination.

Applicants are reminded that for ease of examination, amending existing claims with underlining and bracketing is preferred over canceling existing claims then adding similar new claims.

The introductory paragraph of applicants' response should provide support for all limitations in amendments by page and line number. To expedite prosecution, each new limitation in each claim should be discussed in order. E.g. "the phrase 'DNA molecule' in claim 1 has support on…." "The phrase 'testing a hatched chick for the presence of the transgene' in claim 1 has support on…." "The phrase 'developing… …maturity' in claim 1 has support on…." Otherwise, the examiner has to piece together the response filed 1-24-08 to find where applicants discuss support for each new phrase.

Applicant's arguments filed 1-24-08 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The application contains patent application numbers that will have to be updated upon being allowed or abandoned (e.g. pg 24, pg 92, pg 96).

Claim Rejections - 35 USC § 112

Enablement

Claims 1-15, 17-29, 31 remain and 53-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing transgenic avians comprising microinjecting into a cell of an avian embryo a nucleic acid comprising a transgene comprising a nucleotide sequence encoding a heterologous polypeptide; introducing the microinjected avian embryo into an oviduct of a recipient hen, such that the recipient hen lays a shelled egg containing the microinjected avian embryo; incubating the shelled egg containing the microinjected avian embryo until the egg hatches; testing a hatched chick for the presence of the transgene; and developing a chick that tests positive for the transgene to sexual maturity does not reasonably provide enablement for using any “tissue-specific promoter” (6), a “heterologous polypeptide… …optimized for codon usage by an avian” (claim 9), a transgene comprising “at least two nucleotide sequences each encoding a heterologous polypeptide” (11 and 12), “that form a multimeric protein” (claim 12), that “specifically bind a selected ligand” (13), that is an “antibody” (14) and for using BAC (14) to obtain transgenic avians. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 1 is directed toward making a transgenic avian by microinjecting a nucleotide sequence into an avian embryo or germinal disc to produce a transgenic avian. The claim is limited to making germline transgenic avians.

The Declarations by Dr. Christmann and the Declaration by Dr. Leavitt filed in parent application 10/251364 were filed with applicants' response filed 1-24-08.

The specification does not enable any "tissue specific promoter" as claimed (6, 59). The specification defines a "magnum-specific" promoter as "a promoter that is primarily or exclusively active in the tubular gland cells of the avian magnum (pg 13, paragraph 42). No "tissue-specific promoters" have been described in the specification. The CMV promoter and lysozyme promoter described by Harvey, Ivarie and Love, for example were constitute promoters and did not cause expression "primarily or exclusively" in tubular gland cells or magnum. Without such guidance and in view of the absence of such promoters in the art or the specification, it would have required one of skill undue experimentation to isolate such promoters. Deletion of these claims is suggested.

Applicants argue the specification exemplifies using ovomucoid promoter; therefore, applicants conclude the phrase is enabled. Applicants' argument is not persuasive. Nowhere does the specification teach the ovomucoid promoter is specific to a particular type of tissue.

The specification does not enable those of skill to determine a "heterologous polypeptide… …optimized for codon usage by an avian" (claim 9). No teachings are provided in the specification or the art at the time of filing. Accordingly, it would have required those of skill undue experimentation to determine how to do so or to determine when optimized codon usage had been obtained.

Applicants argue the phrase was well understood in the art at the time of filing. Applicants' argument is not persuasive. The specification and the art at the time of filing did not teach when codon usage was optimized for avians.

The specification does not enable using a transgene comprising "at least two nucleotide sequences each encoding a heterologous polypeptide" (11 and 12), "that form a multimeric protein" (claim 12), that "specifically bind a selected ligand" (13), that is an "antibody" (14) to obtain transgenic avians. The only two nucleotide sequences possible contemplated for use together are two nucleic acid sequences encoding different chains of an antibody. However, the specification does not provide adequate guidance such that the nucleic acids each express an antibody chain in such a way that the proteins recombine to form a functional multimeric protein. Accordingly, it would have required those of skill undue experimentation to determine how to do so.

Applicants argue the claim is enabled because examples 37 and 38 (pg 107) exemplify production of such a heterologous protein. Applicants' argument is not persuasive. Example 38 teaches injecting a vector encoding a heavy and light chain cDNA of the IgG1 kappa monoclonal antibody. Example 38 does not teach the heavy and light chain form a multimeric protein in the chicken once they are expressed.

The specification does not enable using BAC expression vectors to make transgenic avians (claims 15, 29). The art at the time of filing was limited to making transgenic chickens using plasmids or viral vectors. While BAC vectors were known in the art for use in manipulating large genomic sequences (pg 44, last part of paragraph 75), it was unknown whether BAC vectors would stably transfect chicken embryos such that transgenic chickens were obtained. The specification does not correlate the difference in size of the BAC vectors with plasmids or viral particles known in the art to successfully produce transgenic chickens. Without such guidance and in view of the lack of correlation between plasmids and viral particles known in the art capable of producing transgenics and BAC vectors, it would have required one of skill undue experimentation to use BAC promoters to obtain transgenic chickens because BAC vectors may not work. Cancellation is suggested.

Applicants point to pg 107-108, Examples 37 and 38, which teach using a BAC vector. Applicants' argument is not persuasive. The examples do not teach offspring of the transgenic chicken test positive for the transgene after sexual maturity as claimed.

Indefiniteness

Claims 1-15, 17-29, 31 remain and 53-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejections of claims 1-3 and 7, 8, 16, 17 have been withdrawn in view of the amendment.

Claim 6 is indefinite because the metes and bounds of a "tissue specific promoter" are not defined in the specification or the art at the time of filing. Applicants argue the term was well known in the art at the time of filing because a Google search of the term resulted in over 180,000 hits. Applicants' argument is not persuasive because it does not teach the phrase had an art-defined meaning at the time of filing.

Claim 9 is indefinite because the metes and bounds of a coding sequence that is "optimized for codon usage by an avian" are unclear. The metes and bound of such coding sequences cannot be envisioned. In particular, the structure of such coding sequences and the process used to optimize such coding sequences cannot be envisioned.

Applicants argue the phrase was well understood in the art at the time of filing. Applicants' argument is not persuasive. The specification and the art at the time of filing did not teach when codon usage was optimized for avians. Applicants point to Elton, Ikemura, Sharp and Nakamura none of whom define when codon usage is optimized for usage by an avian. While the concept of altering the codons to some advantage, the metes and bounds of when codon usage was optimized was not defined by those of skill in the art. In particular, the metes and bounds of when codon usage was optimized for use in avians was not defined in the art at the time of filing or by applicants.

Claim Rejections - 35 USC § 103

The rejection of claims 1-9, 11 and 18 under 35 U.S.C. 103(a) as being unpatentable over Tanaka (1994, J. Reprod. Fert., Vol. 100, pg 447-449) in view of Naito (Transgenic Animals: Generation and Use, 1997, Ed. By Louis Marie Houdebine, Harwood Academic Publishers, pg 69-73) and Love (Bio/Techn., Jan. 12, 1994, Vol. 12, pg 60-63) has been withdrawn in view of the amendment. In particular, Tanaka placed sperm on a chicken ovum that had been removed from the abdominal cavity or infundibulum of a hen and placed in culture medium (pg 447, col. 2, “Materials and Methods”; pg 448, Fig. 1). The day old fertilized ovum was transferred into the birth canal of a recipient hen. A shell formed around the fertilized ovum as it passed through the recipient hen's reproductive system, and the eggs were laid on the day following transfer (pg 448, col. 1, line 4). Twenty eggs were obtained, three of which hatched and three died during incubation. One embryo expressed the protein but the hatchlings did not (last paragraph of Tanaka). Therefore, Tanaka obtained eggs comprising embryos that tested positive for the transgene but did not maintain the embryo until hatch to become a transgenic chick that tested positive for the transgene until sexual maturity as claimed. In other words, Tanaka did not obtain a chicken whose genome comprised an exogenous nucleic acid sequence in its germ cells that passed the nucleic acid on to its offspring. The combined teachings of Tanaka, Naito and Love do not provide adequate guidance to develop a chick that tests positive for the transgene until sexual maturity as claimed.

The rejection of claims 1-7, 9, 11-13, 19-22 and 25-27 under 35 U.S.C. 103(a) as being unpatentable over Harvey (Nature Biotech., April 2002, Vol. 19, pg 396-399) in view of Tanaka (1994, J. Reprod. Fert., Vol. 100, pg 447-449) has been withdrawn. The claims have priority to provisional application 60/351550 (1-25-02) in view of the claims of ‘550. Accordingly, Harvey is not available as prior art.

Claims 1-14, 18-22, 25-27 and 31 remain rejected and 53-62, 64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivarie (US Patent 6,730,822) in view of Tanaka (1994, J. Reprod. Fert., Vol. 100, pg 447-449) for reasons of record.

Ivarie produced exogenous interferon alpha or erythropoietin protein in an egg of a chicken, which method comprises: a) providing an avian leukosis viral vector comprising a nucleic acid sequence encoding an exogenous interferon alpha or erythropoietin protein, and a constitutive promoter operably linked to said sequence, wherein said promoter drives expression of the encoding sequence in the chicken oviduct; b) introducing said vector into chicken stage X embryonic cells; c) incubating said embryonic cells under conditions conducive to hatching live chicks; d) nurturing growth of a mature chimeric chicken from said chicks; e) mating said chimeric chicken, either naturally or via artificial insemination, with a non-transgenic chicken; f) identifying a transgenic chicken by screening the progeny of step e) for germ line incorporation of the protein encoding sequence; and g) mating the transgenic progeny with non-transgenic chickens to produce eggs containing the exogenous protein (claim 1). The protein could be extracted from the egg (claim 4 of Ivarie). The virus was microinjected as claimed because it was introduced using a glass capillary (col. 20, lines 45-50 of ‘822 states the virus was injected using the method of Thoraval; Thoraval teaches injecting virus into the embryo using a glass capillary on pg 370, col. 2, 2nd full ¶). The virus had a CMV promoter (col. 19, Ex. 1). The offspring “tested positive for the transgene to sexual maturity” because they produced exogenous protein in their egg white (Examples 4 and 5). The virus was injected into the subgerminal cavity (Thoraval, pg 370, col. 2, 2nd full ¶), which is equivalent to injecting the “germinal disc” as claimed because the subgerminal cavity is below the germinal disc and is accessed by injecting the germinal disc. Ivarie did not teach the embryos were introduced into an oviduct of a recipient hen. Ivarie did not teach the nucleic acid sequence was part of a DNA molecule.

However, Tanaka taught delivering DNA to an embryo, then delivering the embryo to the oviduct of a recipient hen (pg 449, col. 1, last ¶). The embryo hatched and became a chick (pg 447, col. 2, "Materials and Methods;" pg 448, Fig. 1; pg 448, col. 1, line 4; pg 448, col. 2, 1st full ¶, line 9).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to deliver a vector encoding an exogenous protein under the control of the CMV promoter into an embryo by glass capillary and allow the embryo to become a chick as taught by Ivarie wherein the vector was DNA and the embryo was introduced into a recipient hen's oviduct as described by Tanaka. One of ordinary skill in the art at the time the invention was made would have been motivated to use DNA and to transplant the embryo of Ivarie into the oviduct of a recipient hen to provide the most natural environment for the embryo and to avoid artificial methods of incubating the embryo in media in a host shell.

The Stage X embryo described by Ivarie is an "early stage embryo" (claim 1) because the metes and bounds of what applicants consider early are unclear (see 112/2nd).

The virus could also have the Ovalbumin promoter (Fig. 2A; Fig. 2C; Fig. 6B) (claim 64).

The technique described by Ivarie inherently results in expression, specifically in the magnum, because the CMV promoter is a constitutive promoter and because cells in the magnum had the transgene in their genome (col. 8, lines 4-10).

The CMV promoter is a “tissue specific promoter” (claim 6) because it provides expression of the exogenous protein in the egg white and serum.

The CMV promoter is a promoter “specific for magnum tissue” (claim 7) because it is provides expression of the exogenous protein in the egg white and meets the definition of “magnum-specific” in col. 15, lines 48-52, of Ivarie and because cells in the magnum had the transgene in their genome (col. 8, lines 4-10).

Claim 9 is included because the metes and bounds of a coding sequence that is “optimized form codon usage by a chicken” are unclear.

Claims 10 and 31 are included because the virus of Ivarie had an IRES (Fig. 2F).

Claims 12, 25 and 26 are included because the virus of Ivarie encoded neo and gene X (Fig. 2A and 2F).

Claims 14 and 28 are included because Ivarie taught the vector could encode an antibody (col. 19, lines 24-42).

Applicants argue it would be counter-intuitive to reintroduce the embryo back into the chicken for in ovo incubation. Applicants' argument is not persuasive. Introducing the embryo back into the chicken was known in the art as described by Tanaka. One of ordinary skill in the art at the time the invention was made would have been motivated to transplant the embryo of Ivarie into the oviduct of a recipient hen to provide the most natural environment for the embryo and to avoid artificial methods of incubating the embryo in media in a host shell.

Double Patenting

The provisional rejection of claims 1-15 and 18-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of copending Application No. 10/251364 in view of the disclosure of ‘364 has been withdrawn in view of the terminal disclaimer filed 1-24-08.

Claims 1-15, 18-29 and 53-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of US Patent 7,381712 (Application No. 10/842606) in view of the disclosure of ‘712. ‘712 claims a method of producing a transgenic avian comprising: delivering a nucleic acid solution under pressure to oviduct tissue of an avian by administering the nucleic acid solution to an anterior oviductal, inferior uterine, superior uterine or middle uterine artery such that the nucleic acid enters a cell of the oviduct tissue and is expressed, thereby producing a transgenic avian. The subject matter now claimed in the instant application but not claimed in ‘712 is in the disclosure of ‘712. Thus, it would have been obvious to perform the method claimed in ‘712 using the limitations now claimed. Applicants argue the claims do not overlap but provide no reasoning. Applicants' argument is not persuasive for reasons cited in the basis of the rejection.

Claims 1-15 and 18-29 remain and claims 53-68 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 11/337361 in view of the disclosure of ‘361. ‘361 claims a method comprising recovering from an avian egg a protein wherein the protein is exogenous to the egg. The subject matter now claimed in the instant application but not claimed in ‘361 is in the disclosure of ‘361. Thus, it would have been obvious to perform the method claimed in ‘361 using the limitations now claimed. This is a provisional obviousness-type double patenting rejection. Applicants argue the claims do not overlap but provide no reasoning. Applicants' argument is not persuasive for reasons cited in the basis of the rejection.

Claims 1-15 and 18-29 remain and claims 53-68 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 11/376023 in view of the disclosure of ‘023. ‘023 claims a method comprising recovering from an avian egg a protein wherein the protein is exogenous to the egg. The subject matter now claimed in the instant application but not claimed in ‘023 is in the disclosure of ‘023. Thus, it would have been obvious to perform the method claimed in ‘023 using the limitations now claimed. This is a provisional obviousness-type double patenting rejection. Applicants argue the claims do not overlap but provide no reasoning. Applicants' argument is not persuasive for reasons cited in the basis of the rejection.

Claims 1-14 and 19-28 remain and claims 53-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,730,822 (US Application 10/, in view of the disclosure of ‘822, and Tanaka (1994, J. Reprod. Fert., Vol. 100, pg 447-449). ‘822 claimed a method for producing an exogenous interferon alpha or erythropoietin protein in an egg of a chicken, which method comprises: a) providing an avian leukosis viral vector comprising a nucleic acid sequence encoding an exogenous interferon alpha or erythropoietin protein, and a constitutive promoter operably linked to said sequence, wherein said promoter drives expression of the encoding sequence in the chicken oviduct; b) introducing said vector into chicken stage X embryonic cells; c) incubating said embryonic cells under conditions conducive to hatching live chicks; d) nurturing growth of a mature chimeric chicken from said chicks; e) mating said chimeric chicken, either naturally or via artificial insemination, with a non-transgenic chicken; f) identifying a transgenic chicken by screening the progeny of step e) for germ line incorporation of the protein encoding sequence; and g) mating the transgenic progeny with non-transgenic chickens to produce eggs containing the exogenous protein (claim 1). The protein could be extracted from the egg (claim 4 of ‘822). ‘822 did not claim the virus was microinjected, the virus had a CMV promoter, the offspring produced exogenous protein in their magnum or egg white, or that the nucleic acid was injected into the germinal disc.

However, ‘822 taught the many other limitations currently claimed that could have been claimed in ‘822 based on the disclosure of ‘822. The virus of ‘822 was microinjected as claimed because it was introduced using a glass capillary (col. 20, lines 45-50 of ‘822 states the virus was injected using the method of Thoraval; Thoraval teaches injecting virus into the embryo using a glass capillary on pg 370, col. 2, 2nd full ¶). The virus had a CMV promoter (col. 19, Ex. 1). The offspring produced exogenous protein in their egg white (Examples 4 and 5). The virus was injected into the subgerminal cavity (Thoraval, pg 370, col. 2, 2nd full ¶), which is equivalent to injecting the “germinal disc” as claimed because the subgerminal cavity is below the germinal disc and is accessed by injecting the germinal disc. The Stage X embryo described by Ivarie is an “early stage embryo” (claim 2) because the metes and bounds of what applicants consider early are unclear (see 112/2nd). The virus could also have the Ovalbumin promoter (Fig. 2A; Fig. 2C; Fig. 6B), which is magnum specific (claim 7). The technique described by Ivarie inherently results in expression specifically in the magnum as in claim 7 because the CMV promoter is a constitutive promoter and because cells in the magnum had the transgene in their genome (col. 8, lines 4-10). The CMV promoter is a “tissue specific promoter” (claim 6) because it provides expression of the exogenous protein in the egg white. The CMV promoter is also a promoter “specific for magnum tissue” (claim 7) because it is provides expression of the exogenous protein in the egg white and meets the definition of “magnum-specific” in col. 15, lines 48-52, of Ivarie and because cells in the magnum had the transgene in their genome (col. 8, lines 4-10). Claim 9 is included because the metes and bounds of a coding sequence that is “optimized form codon usage by a chicken” are unclear. Claim 10 and 24 are included because the virus had an IRES (Fig. 2F). Claims 11-13 and 25-27 are included because the virus encoded neo and gene X (Fig. 2A and 2F). Claims 14 and 28 are included because Ivarie taught the vector could encode an antibody (col. 19, lines 24-42). Thus, it would have been obvious to perform the methods claimed in ‘822 using the specific limitations now claimed based on the disclosure of ‘822. ‘822 did not teach the embryos were introduced into an oviduct of a recipient hen as required in claims 1 and 20 in the instant application.

However, Tanaka (1994, J. Reprod. Fert., Vol. 100, pg 447-449) taught delivering DNA to an embryo, then delivering the embryo to the oviduct of a recipient hen (pg 449, col. 1, last ¶). The embryo hatched and became a chick (pg 447, col. 2, "Materials and Methods;" pg 448, Fig. 1; pg 448, col. 1, line 4; pg 448, col. 2, 1st full ¶, line 9).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to deliver virus encoding an exogenous protein under the control of the CMV promoter into an embryo by glass capillary and allow the embryo to become a chick as taught by '822 wherein the embryo was introduced into a recipient hen's oviduct as described by Tanaka. One of ordinary skill in the art at the time the invention was made would have been motivated to transplant the embryo of '822 into the oviduct of a recipient hen to provide the most natural environment for the embryo and to avoid artificial methods of incubating the embryo in media in a host shell.

Applicants argue the rejection should be withdrawn for reasons provided under 103 for Ivarie in view of Tanaka. Applicants' arguments were not persuasive.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Patent Examiner